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PATENT  
0020-4771P

IN THE U.S. PATENT AND TRADEMARK OFFICE

Applicant: SANO et al. Conf.: 8796  
Appl. No.: 09/701,303 Group: 1615  
Filed: November 28, 2000 Examiner: R. M. JOYNES  
For: CONTROLLED RELEASE PREPARATIONS HAVING  
MULTI-LAYER STRUCTURE

INFORMATION DISCLOSURE STATEMENT  
(SUBMISSION AFTER FILING OF AN APPLICATION  
BUT BEFORE FINAL REJECTION OR NOTICE OF ALLOWANCE  
OR CONCURRENTLY WITH A RULE 1.114 RCE APPLICATION)

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

April 7, 2004

Sir:

Pursuant to 37 C.F.R. §§ 1.97 and 1.98, applicant(s) hereby submit(s) an Information Disclosure Statement for consideration by the Examiner.

I. LIST OF PATENTS, PUBLICATIONS OR OTHER INFORMATION

The patents, publications, or other information submitted for consideration by the Office are listed on the PTO-1449(s), attached hereto.

II. COPIES (check at least one box)

- a. ☒ This application was filed before June 30, 2003. Accordingly, submitted herewith is a legible copy of (i) each U.S. and foreign patent; (ii) each publication or that portion which caused it to be listed; and (iii) all other information or that portion which caused it to be listed.
- b. ☐ This application was filed on or after June 30, 2003. Accordingly, copies of cited U.S. patents and patent application publications therefore are not included. Copies of foreign patent documents and non-patent literature are included.

- c. ☐ Some or all of the documents listed on the PTO-1449 are not enclosed because they were cited in the International Search Report and copies should already be in the PTO file. If copies are needed, please contact the undersigned.

III. CONCISE EXPLANATION OF THE RELEVANCE  
(check at least one box)

- a. ☒ **DOCUMENTS IN THE ENGLISH LANGUAGE**

The patents, publications, or other information listed on the attached PTO 1449 are in the English language and therefore, do not require a statement of relevancy.

- b. ☐ **DOCUMENTS NOT IN THE ENGLISH LANGUAGE**

A concise explanation of the relevance of all patents, publications, or other information listed that is not in the English language is as follows:

- c. ☒ **ENGLISH LANGUAGE SEARCH REPORT**

An English language version of the search report or action that indicates the degree of relevance found by the foreign office is attached, thereby satisfying the requirement for a concise explanation. See MPEP 609(III)(A)(3).

- d. ☐ **OTHER**

The following additional information is provided for the Examiner's consideration.

FEES

IV. ☐ THIS IDS IS BEING FILED UNDER 37 C.F.R. § 1.97(b):  
(check one box)

- a. ☐ within three months of the filing date of a national application (37 C.F.R. § 1.97(b)(1)). No fee or statement is required. *(This section is not to be used with RCE's.)*
- b. ☐ within three months of the date of entry of the national stage as set forth in § 1.491 in an international application (37 C.F.R. § 1.97(b)(2)). No fee or statement is required.
- c. ☐ concurrently with the filing of a Request for Continued Examination under § 1.114 (37 C.F.R. § 1.97(b)(4)). No fee or statement is required.
- d. ☐ before the mailing date of a first Action on the merits (37 C.F.R. § 1.97(b)(3)). No fee or statement is required.  
In the event that a first Office Action on the merits has been issued, please consider this IDS under 37 C.F.R. § 1.97(c) and see the statement under 37 C.F.R. § 1.97(e) below, or, if no statement has been made, charge our deposit account in the amount of \$180.00 as required by 37 C.F.R. § 1.17(p).

V. ☒ THIS IDS IS BEING FILED UNDER 37 C.F.R. § 1.97(c):  
(check one box)

before the mailing date of a Final Office Action under 37 C.F.R. § 1.113 (See 37 C.F.R. § 1.97(c)(1)) or before the mailing date of a Notice of Allowance under 37 C.F.R. § 1.311 (See 37 C.F.R. § 1.97(c)(2)).

- a. ☒ No statement; therefore, a fee in the amount of \$180.00 as required by 37 C.F.R. § 1.17(p).  
or
- b. ☐ See the statement below. No fee is required.

VI. STATEMENT UNDER 37 C.F.R. § 1.97(e) (check only one box)

The undersigned hereby states that

- a. ☐ each item of information contained in the IDS was first cited in any communication from a foreign Patent Office in a counterpart foreign application not more than three months prior to the filing of this IDS; or
- b. ☐ no item of information contained in the IDS was cited in a communication from a foreign Patent Office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of IDS was known to any individual designated in 37 C.F.R. § 1.56(c) more than three months prior to the filing of the IDS.
- c. ☐ Some of the items of information were cited in a communication from a foreign Patent Office. As to this information, the undersigned states that each item of information contained in the IDS was first cited in a communication from a foreign Patent Office in a counterpart foreign application not more than three months prior to the filing of this IDS. As to the remaining information, the undersigned hereby states that no item of this remaining information contained in the IDS was cited in a communication from a foreign Patent Office in a counterpart foreign application and, to the best of my knowledge after making reasonable inquiry, was known to any individual designated in 37 C.F.R. § 1.56(c) more than three months prior to the filing of this statement.

VII. PAYMENT OF FEES (check one box)

- ☒ A check in the amount of \$180.00 as required by 37 C.F.R. § 1.17(p) is enclosed for the above-identified fee.
- ☐ Please charge Deposit Account No. 02-2448 in the amount required by 37 C.F.R. § 1.17(p) for the above-indicated fee. A triplicate copy of this paper is attached.
- ☐ No fee is required.

Appl. No. 09/701,303

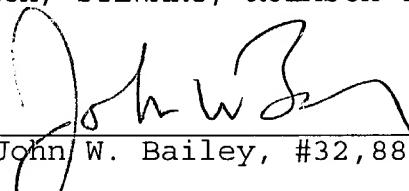
If the Examiner has any questions concerning this IDS, he/she is requested to contact the undersigned. If it is determined that this IDS has been filed under the wrong rule, the PTO is requested to consider this IDS under the proper rule and charge the appropriate fee to Deposit Account No. 02-2448.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to Deposit Account No. 02-2448 for any additional fees required under 37 C.F.R. § 1.16 or under § 1.17; particularly, extension of time fees.

Respectfully submitted,

BIRCH, STEWART, KOLASCH & BIRCH, LLP

By

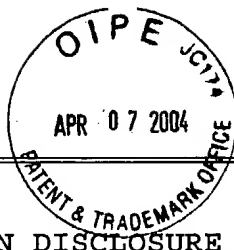
  
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JWB/enm  
0020-4771P

Attachment(s): ☒ PTO-1449  
☒ Documents  
☒ Foreign Search Report  
☒ Fee  
☐ Other:

(Rev. 02/12/2004)



Form PTO-1449

**INFORMATION DISCLOSURE CITATION  
IN AN APPLICATION**

(Use several sheets if necessary)

ATTY. DOCKET NO.  
0020-4771PAPPLICATION NO.  
09/701,303APPLICANT  
SANO et al.FILING DATE  
November 28, 2000GROUP  
1615**U.S. PATENT DOCUMENTS**

EXAMINER INITIAL	DOCUMENT NUMBER	Kind	DATE	NAME	CLASS	SUB CLASS	FILING DATE IF APPROPRIATE
	US						
	US						
	US						
	US						
	US						
	US						
	US						
	US						
	US						
	US						

**FOREIGN PATENT DOCUMENTS**

	Office	DOCUMENT NUMBER	Kind	DATE	COUNTRY	CLASS	SUB CLASS	TRANSLATION	
								YES	NO

**OTHER DOCUMENTS** (Include Name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.) date, page(s), volume-issue number(s), publisher, city and/or country where published.)

MAEDA et al., J. of Controlled Release, Vol. 62, pp. 313-324, (1999).

BUDAVARI et al., The Merck Index, 12<sup>th</sup> Edition, pp. 742-743, (1996).

KAJIHARA et al., J. of Controlled Release, Vol. 66, pp. 49-61, (2000).

EXAMINER

DATE CONSIDERED

EXAMINER: Initial if citation considered, whether or not citation is in conformance with M.P.E.P. 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.



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09. März 2004

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(Formalities and other matters)



R



GK 1357 6642 7DE

Application No. 99 921 162.6 - 2123	Ref. E 2923 EP	Date 08.03.2004
Applicant Sumitomo Pharmaceuticals Company, Limited		

**Communication pursuant to Article 96(2) EPC**

The examination of the above-identified application has revealed that it does not meet the requirements of the European Patent Convention for the reasons enclosed herewith. If the deficiencies indicated are not rectified the application may be refused pursuant to Article 97(1) EPC.

You are invited to file your observations and insofar as the deficiencies are such as to be rectifiable, to correct the indicated deficiencies within a period

**of 2 months**

from the notification of this communication, this period being computed in accordance with Rules 78(2) and 83(2) and (4) EPC.

One set of amendments to the description, claims and drawings is to be filed within the said period on separate sheets (Rule 36(1) EPC).

**Failure to comply with this invitation in due time will result in the application being deemed to be withdrawn (Article 96(3) EPC).**



BORST M M  
Primary Examiner  
for the Examining Division

Enclosure(s): 2 page/s reasons (Form 2906)



Datum  
Date 08.03.2004  
Date

Blatt  
Sheet 1  
Feuille

Anmelde-Nr.:  
Application No.: 99 921 162.6  
Demande n°:

The examination is being carried out on the **following application documents**:

### Description, Pages

1-26 as originally filed

### Claims, Numbers

1-6 received on 16.02.2004 with letter of 16.02.2004

### Drawings, Sheets

1/5-5/5 as originally filed

- D1: EP-A-0 722 656
- D2: DATABASE WPI Section Ch, Week 199305 Derwent Publications Ltd., London, GB; Class B07, AN 1993-039771 XP002185698 & JP 04 364120 A (KOKEN KK), 16 December 1992 (1992-12-16)
- D3: EP-A-0 659 406 (SUMITOMO PHARMA ;DOW CORNING ASIA LTD (JP)) 28 June 1995 (1995-06-28)
- D4: EP-A-0 009 410 (LILLY CO ELI) 2 April 1980 (1980-04-02)
- D5: EP-A-0 306 212 (LILLY CO ELI) 8 March 1989 (1989-03-08)
- D6: Maeda M et al. "Microstructure..." Journal of Controlled Release 62 (1999) 313-324, page 314, left-hand column, first full paragraph
- D7: Budavari S et al., "The Merck Index" 12th ed., page 742-743" 1996
- D8: Kajihara M. et al. "Development of...", Journal of Controlled Release 66 (2000) page 59, right hand column, lines 13-31

## 1. Inventive step (Article 52(1) and 56 EPC)

The subject-matter of claims 1, 3-6 does not involve an inventive step in the light of D3 and D2.

The closest prior art D3 (page 3, line 52-55; page 7, line 18-27; example 1, 6) discloses rod-like implants, the inner layer of which comprises a water soluble drug and silicone polymer, whereas the outer layer comprises silicone polymer only. According to D3 the outer layer controls water permeation into and channeling/cracking within the inner layer, thus, preventing uncontrolled drug release and providing zero order release from the inner layer over prolonged periods of time. In fact the specific mechanism of releasing the drug as invoked by the Applicant, i.e. not by diffusion, but by channelling and cracking, is already





known from D3. In contrast to the subject-matter of the claims on file the implant of D3 does not comprise drug within the outer layer providing quick release at early stage.

The objective technical problem to be solved in the light of D3 was to develop an implant providing in parallel quick release at early stage and constant release over prolonged periods of time for one single or different drug(s).

Already D3 (page 7, line 18-27) notes that penetration of water into and release of drug from the outer layer is immediate and, thus, directly points to the incorporation of drug into the outer layer for solving the above technical problem. In fact, when considered in the light of D3 no unexpected effect can be seen for the incorporation of drug into the outer layer, since immediate release therefrom was indicated already in D3. Additionally, the concept of controlling the release of two (different concentrations) of drugs from implants by selecting a rod-like structure with concentric drug-containing layers is known from D2. The fact that in case of D2 the release of drug is based on diffusion and not on channelling/cracking does not point away from the subject-matter of the claims on file, since the mode of release was already known from D3 itself.

## 2. Conclusion

Inventive step is a prerequisite for patentability (Article 52(1) EPC). An application defective in this respect is deemed to be refused (Art. 97(1) EPC). The Applicant is, therefore, requested to establish inventive step, for instance by incorporating the feature of an intermediate layer as defined in claim 2 on file. The specific structure comprised of an outer drug-containing layer in combination with an intermediate layer does not appear to be obvious from D3 nor from the abstract of D2 nor from any other document cited. However, since the fulltext version of D2 might contain an indication in this respect, the Applicant is requested to file a translation of the fulltext version of D2 into one of the official languages.